

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

**Children's Products Containing Lead; Proposed
Determinations Regarding Lead Content Limits on Certain
Materials or Products; Notice of Proposed Rulemaking**

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking

SUMMARY: On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314, 122 Stat. 3016. This notice of proposed rulemaking (NPR) initiates a proceeding under section 3 of the CPSIA authorizing the Commission to issue regulations, as necessary, to implement the CPSIA. In this document, the Commission solicits written comments concerning preliminary determinations on certain natural, untreated and unadulterated materials and metals that have not been found to exceed the lead content limits prescribed under section 101(a) of the CPSIA.

DATE: Written comments and submissions in response to this notice must be received by [**insert date that is 30 days after publication**].

ADDRESSES: Comments should be e-mailed to Sec101Determinations@cpsc.gov. Comments should be captioned "Section 101 Determinations of Certain Materials or Products NPR." Comments may also be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814, or delivered to the same address (telephone (301) 504-7923). Comments also may be filed by facsimile to (301)504-0127.

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7254, e-mail khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

Under section 101(a) of CPSIA, consumer products designed or intended primarily for children 12 years old and younger that do not contain more than 600 ppm of lead (as of February 10, 2009), 300 ppm of lead (as of August 14, 2009); 100 ppm after three years (as of August 14, 2011), unless the Commission determines that it is not technologically feasible to have this lower limit, are not considered to be banned hazardous substances under the

Federal Hazardous Substances Act (FHSA). However, in the absence of Commission action, these products and materials remain subject to the testing requirements of section 102 of the CPSIA (codified at § 14 of the Consumer Product Safety Act (CPSA)).

Under these provisions, on and after February 10, 2009, general conformity certificates certifying that they comply with the applicable lead content limit are required for children's products. The certification must be based on tests of each product or a reasonable testing program. On and after August 14, 2009, absent Commission action to the contrary, the certificates must be based on testing performed by a laboratory whose accreditation to perform the testing has been accepted by the Commission.

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. There may be certain products or materials that inherently do not contain lead or contain lead at levels that do not exceed the lead content limits under section 101(a) of the CPSIA. To the extent that such materials or products exist, the Commission, of its own initiative, is proposing to exercise its section 3 authority to make preliminary determinations that certain commodities or classes of materials or products do not

exceed the lead limits prescribed in section 101(a) of the CPSIA. The effect of such a Commission finding would be to relieve the material or product from the testing requirement of section 102 of the CPSIA for purposes of supporting the required certification. Of course even where a material or product has been so relieved of the testing requirement, it must still meet the statutory lead level requirements in actual fact. The Commission will obtain and test products in the marketplace to assure that this remains the case and will take appropriate enforcement action in situations where that is not the case.

B. Proposed Determinations on Certain Products and Materials

The Commission staff identified a number of commodities or classes of materials that do not inherently contain lead or contain lead that does not exceed the CPSIA lead limits of 600 ppm or 300 ppm.

Certain Natural Materials

Based on the staff's review, the Commission preliminarily determines that the following natural materials do not exceed the 600 ppm or 300 ppm lead content limits under section 101(a) of the CPSIA. These preliminary determinations are based on materials that are untreated and unadulterated with respect to the addition of

materials or chemicals, including pigments, dyes, coatings, finishes or any other substance, and that do not undergo any processing that could result in the addition of lead into the product or material:

1. Precious gemstones: diamond, ruby, sapphire, emerald

2. Certain semiprecious gemstones provided that the mineral or material is not based on lead or lead compounds and is not associated in nature with any mineral that is based on lead or lead compounds (minerals that contain lead or are associated in nature with minerals that contain lead include, but are not limited to, the following: aragonite, bayldonite, boleite, cerussite, crocoite, linarite, mimetite, phosgenite, vanadinite, and wulfenite)

3. Natural or cultured pearls

4. Wood

5. Natural fibers such as cotton, silk, wool, hemp, flax, linen

6. Other natural materials including coral, amber, feathers, fur, untreated leather

Certain Metals and Alloys

Based on the staff's review, the Commission preliminarily determines that the following metals and alloys do not exceed the 600 ppm or 300 ppm lead content

limits under section 101(a) of the CPSIA provided that no lead or lead-containing metal is intentionally added:

1. Surgical steel
2. Precious metals: gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium

The preliminary determinations do not extend to the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications.

C. Requests for Comments

All interested persons are invited to submit to the Commission their comments and data concerning the Commission's preliminary determinations on the listed natural materials and metals and alloys. In particular, the Commission invites interested persons to submit any test results showing that substances covered by the proposed rule had lead exceeding the lead limits in section 101(a) of the CPSIA. In addition, the Commission seeks comments on:

- Other natural fibers that would not exceed the lead content limits
- Other natural materials that would not exceed the lead content limits

- Other metals or alloys that would not exceed the lead content limits
- Other materials, which by their nature, would not exceed the lead content limits

Comments should be e-mailed to Sec101Determinations@cpsc.gov. Comments should be captioned "Section 101 Determinations of Certain Materials or Products NPR." Comments may also be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814, or delivered to the same address (telephone (301) 504-7923). Comments also may be filed by facsimile to (301)504-0127. All comments and submissions should be received no later than **[insert date that is 30 days after publication]**.

D. Impact on Small Businesses

Under the Regulatory Flexibility Act (RFA), when an agency issues a proposed rule, it generally must prepare an initial regulatory flexibility analysis describing the impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of relieving certain materials or products from the testing requirements of section 102 of the CPSIA if they were found to be inherently under the lead content limits prescribed. The number of small businesses that will be directly affected by the rule is unknown but could be considerable. However, it will not result in any increase in the costs of production for any firm. Its only effect on businesses, including small businesses, will be to reduce the costs that would have been associated with testing the materials under section 102 of the CPSIA. Based on the foregoing assessment, the Commission preliminarily finds that the proposed rule would not have a significant impact on a substantial number of small entities.

E. Environmental Considerations

Generally, CPSC rules are considered to "have little or no potential for affecting the human environment," and environmental assessments are not usually prepared for these rules (see 16 CFR 1021.5(c)(1)). The proposed rule will not result in any additional lead in the environment since such materials do not contain lead or contain lead at levels that do not exceed the CPSIA limits. Therefore, the

Commission does not expect the proposed rule to have any negative environmental impact.

F. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of regulations such as this proposal is stated in section 18 of the FHSA. 15 U.S.C. 1261n.

G. Effective Date

The Administrative Procedure Act requires that a substantive rule must be published not less than 30 days before its effective date, unless the rule relieves a restriction. 5 U.S.C. 553(d)(1). Because the proposed rule would provide relief from existing testing requirements under the CPSIA, the proposed effective date is the date of publication of a final rule in the *Federal Register*.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, and Toys.

H. Conclusion

For the reasons stated above, the Commission proposes to amend title 16 of the Code of Federal Regulations as follows:

PART 1500 - HAZARDOUS SUBSTANCES AND ARTICLES:

ADMINISTRATION AND ENFORCEMENT REGULATIONS

1. The authority for part 1500 is amended to read as follows:

Authority: 15 U.S.C. 1261-1278, 122 Stat. 3016

2. Add a new section 1500.91 to read as follows:

§ 1500.91 Determinations Regarding Lead Content for Certain Materials or Products under Section 101 of the Consumer Product Safety Improvement Act.

(a) The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to have this lower limit. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child.

(b) Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as

necessary, either on its own initiative or upon the request of any interested person, to make a determination that a material or product does not exceed the lead limits as provided under (a).

(c) The following natural materials do not exceed the 600 ppm or 300 ppm lead content limits under section 101(a) of the CPSIA provided that these materials have neither been treated or adulterated with the addition of materials or chemicals such as pigments, dyes, coatings, finishes or any other substance, nor undergone any processing that could result in the addition of lead into the product or material:

- (1) Precious gemstones: diamond, ruby, sapphire, emerald
- (2) Semiprecious gemstones provided that the mineral or material is not based on lead or lead compounds and is not associated in nature with any mineral that is based on lead or lead compounds (minerals that contain lead or are associated in nature with minerals that contain lead include, but are not limited to, the following: aragonite, bayldonite, boleite, cerussite, crocoite, linarite, mimetite, phosgenite, vanadinite, and wulfenite).

- (3) Natural or cultured pearls
- (4) Wood
- (5) Natural fibers such as cotton, silk, wool, hemp, flax, linen
- (6) Other natural materials including coral, amber, feathers, fur, untreated leather

(d) The following metals and alloys do not exceed the 600 ppm or 300 ppm lead content limits under section 101(a) of the CPSIA provided that no lead or lead-containing metal is intentionally added but does not include the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications:

- (1) Surgical steel
- (2) Precious metals: gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium

List of Relevant Documents

(1) Memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences "Consumer Product Safety Improvement Act of 2008 (CPSIA): Certain Materials or Products that Do Not Exceed the Limits for Lead Content." December 2008.

(2) Memorandum from Robert Franklin, Economist, Directorate for Economic Analysis, "Preliminary regulatory analysis of a rule making determinations that certain materials or products do not have lead contents that exceed the limits established in section 101(a) of the CPSIA." December 2008.

Dated: January 9, 2009



Todd A. Stevenson, Secretary
Consumer Product Safety Commission